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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/315,355	05/17/1999	SUSAN K. KEESEE	MTP-023DV2	6421

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TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/315,355	Applicant(s) KEESEE ET AL.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,25,50-52,54,55,57,58 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,25,50-52,54,55,57,58 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *17* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on April 23,2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/315,355 is acceptable and a CPA has been established. An action on the CPA follows.

2. The amendment filed March 12, 2003 is acknowledged. Claims 56, 59 and 60 were canceled. Claims 55 and 57 were amended.

Claims 24, 25, 50-52, 54, 55, 57, 58, and 61-63 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Maintained:

4. The amendment filed 7/30/2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The nucleic acid sequence of SEQ ID NO:47 and 48 is not supported by the disclosure as originally filed. Applicant cites for support, page 7, lines 11-15 of the instant specification, which applicant argues incorporates Honore et al. (1994) Gene 151:291-296 by reference. This citation fails to provide support for the nucleic acid sequences because

the portion of the specification that incorporates Honore et al. refers specifically to a protein sequence, IEF SSP 9502, and thus fails to provide support for a nucleic acid sequence.

Applicant's arguments have been carefully considered, but are unpersuasive. The declaration of Duncan Greenhalgh is acknowledged. However, applicant's arguments are unpersuasive, because the MPEP, 608.01(p), states that "... the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to the specific portions of the reference document where the subject mater being incorporated may be found." Therefore, it appears that contrary to what applicant argues, incorporation of a reference does not automatically incorporate the entire teachings of the document, but only the subject matter that is pointed to. At the point in the specification where the Honore reference is incorporated, the specification is teaching the use of the detection of a protein having the sequence of SEQ ID NO: 10, appears to rely on Honore as a reference to show that SEQ ID NO: 10 is known in the art as IEF SSP 9502. Therefore, it appears that specification incorporated Honore for the purpose of teaching the protein sequence, and not for any other teaching that may be found in the reference.

Applicant is required to cancel the new matter in the reply to this Office action.

5. Claims 24, 25, 50-52, 54, 55, 57, 58 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to methods that comprise either detecting SEQ ID NO: 47, or its complement, detecting a complex of a nucleic acid or a peptide nucleic acid that binds to SEQ ID

NO: 47, detecting a nucleic acid that binds to SEQ ID NO: 47 or detecting a nucleic acid that hybridizes to SEQ ID NO: 47. The nucleic acid sequence of SEQ ID NO: 47 is not supported by the disclosure as originally filed. Applicant cites page 7, lines 11-15 of the specification, for support of the claims. Applicant argues the incorporation by reference of Honore et al. (1994) Gene 151:291-296 supplies the sequence of SEQ ID NO: 47, and that because Honore is incorporated by reference that the entire disclosure of Honore is incorporated into the specification. As discussed above, this argument is not found persuasive, because the MPEP teaches that incorporation by reference incorporates specific portions of the reference document. Therefore, it does not appear that applicant was in possession of the claimed invention, because the claimed invention is drawn to methods that comprise detection of species that were not disclosed at the time of filing.

6. Claims 24, 25, 50-52, 55, 57, 58, 61 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detection of mRNA that encodes a protein of SEQ ID NO: 10 for the purpose of diagnosing cervical cancer, does not reasonably provide enablement for methods of detection of genomic DNA for the purpose of diagnosing cervical cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence

or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

Claim 24 is drawn to methods comprising detection of SEQ ID NO: 47 or a sequence complementary thereto. The claim fails to recite that the complementary sequence is fully complementary. Thus, claim 24 reads on the detection of genomic DNA that is complementary to SEQ ID NO: 47, which appears to be a cDNA sequence. Claim 55 is drawn to methods for detecting cervical cancer comprising detecting a complex of a binding moiety and a target nucleic acid, wherein the binding moiety is a nucleic acid or a peptide nucleic acid, and the binding moiety binds specifically to a nucleic acid having a nucleotide sequence of SEQ ID NO: 47. It appears that SEQ ID NO: 47 is a cDNA sequence. Thus, the binding moiety could bind to genomic DNA if it binds to SEQ ID NO: 47. The claims do not recite that the binding moiety hybridizes to the full length of SEQ ID NO: 47, only that it binds specifically. There are no size limitations on the binding moiety. Thus, a binding moiety that is specific for a part of SEQ ID NO: 47 would also bind specifically to a part of the genomic DNA that encodes SEQ ID NO: 10. Therefore, claim 55 reads on the detection of genomic DNA sequences. Claim 62 is drawn to methods for detecting cervical cancer comprising detecting a nucleic acid molecule that specifically binds a sequence complementary to SEQ ID NO: 47 or a nucleic acid molecule that hybridizes to a sequence complementary to SEQ ID NO: 47. Claim 62 reads on methods that detect genomic DNA sequences because, in sections (i) and (ii), the method comprise the detection of a nucleic acid that binds a sequence complementary to SEQ ID NO: 47. Thus, it appears that a complement of SEQ ID NO: 47 (which is a cDNA sequence) is used a probe.

Such a probe would bind to genomic DNA. Furthermore, because of the lack of size limitation, it could bind under highly stringent conditions.

To the extent the claimed inventions encompass methods that comprise the detection of genomic DNA for the purpose of detecting cervical cancer, the claimed inventions are not supported by the specification. The specification teaches that a protein, CvC-3 is detectable in cervical cancer samples, but not detectable in normal cervical tissues. The specification further teaches that CvC-3 comprises two separate proteins, one of which comprises the amino acid sequence of SEQ ID NO: 10. Thus, it appears possible that mRNA nucleic acid encoding SEQ ID NO: 10 would be expressed at higher levels in cervical cancer samples, and at lower levels or, not at all, in non-cancerous samples. The detection of differential protein expression between cancerous and normal tissues, however, teaches one nothing with respect to whether the detection of genomic DNA could be used as a basis for the detection of cervical cancer. The specification provides no justification to assume that SEQ ID NO: 10 is a mutated protein, having a unique coding sequence that is not found in non-cancerous cervical tissue. Therefore, the genomic coding sequence would be detectable in both cancerous and non-cancerous cervical tissues.

Because the claimed inventions read on detection of genomic DNA, and because the specification fails to provide any evidence that detection of genomic DNA could be used as a basis for the detection of cervical cancer, the specification fails to enable one of skill in the art to practice the full scope of the claimed invention with a reasonable expectation of success.

New Grounds of Rejection:

7. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is indefinite because it lacks antecedent basis for "the nucleic acid" in claim 55. Claim 55 refers to two nucleic acid molecules, a binding moiety and a target nucleic acid.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
July 28, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600